K132178

APR 30 2014

510(K) SUMMARY

Submitter:
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Device Information
Device Name: Mostdi Dental Implant System
Classification Name: Endosseous dental implant
Common Name: Dental implant
Panel: Dental
Classification: Class II
Product Code: DZE
Regulation number: 21 CFR 872.3640
Date prepared: 7/10/2013

General Description

Mostdi™ dental implant system consists of one piece screw type endosseous dental implants manufactured from titanium alloy and intended to provide support for prosthetic devices such as bridges and removable dentures in order to restore a patient's chewing function.

Indications for Use

The Mostdi ™ dental implants are indicated to provide support for removable dentures, and fixed bridges for the treatment of partial or full edentulism. Multiple implants are to be used and can be immediately loaded if good primary stability is achieved and with appropriate occlusal loading.

Testing

The following were reviewed to support the performance of Mostdi™ dental implants: Fatigue tests to ISO 14801/ static test, sterilization validation, shelf life testing, surface analysis & biocompatibility testing.

Substantial Equivalence

Areas of Comparison	Mostdi Dental Implant System	Intra-Lock® OP Dental Implants	Mini Drive-Lock™ Dental Implant System	Lew Mini O-Ball Implant	IMTEC Sendax MDI and MDI Plus
Regulatory Status	Present Application	Predicate	Predicate	Predicate	Predicate
510(k) Number	K132178	K130140	K070601	K121707	K031106
Meterial	Ti6Al4V ASTM F-136	Ti6Al4V ASTM F-136	Ti6Al4V ASTM F-136	Ti6Al4V ASTM F-136	Ti6Al4V ASTM F-136
One Piece/ Two Piece Type Implant	One piece	One piece	One piece	One piece	One piece
Surface	Roughened – light sand blast & acid etch	Blasted	N/A	Blasted and clean (SLA equivalent), machined surface, SE to IMTEC K031106	N/A
Dimensions (mm)	OBH: 2.5, 3.0 diameter and 8,10,12,13,14,16 threaded length MXO: 3.5 diameter and 8, 10 threaded length PEO: 3.6 diameter in 10, 12, 14, 16, 18 threaded length PDH: 2.5, 3.0 diameter in 8, 10, 12, 13, 14, 16 threaded length MXP: 3.5 diameter for 8, 10 threaded length PEP: 3.8 diameter for 10, 12, 14, 16, 18 threaded length	3.0, 3.75, 4.0, 4.75 diameter, 10 – 15 threaded length	2.0, 2.5 diameter, 10, 11.5, 13, 15, 18 threaded length	2.0, 2.5, 3.0 diameter, 10, 13, 15, 17, 18 threaded length	N/A
Product Code	DZE	DZE	DZE	DZE	DZE
Indications for Use	The Mostdi ™ dental implants are indicated to provide support for removable dentures, and fixed bridges for the treatment of partial or full edentulism. Multiple implants are to be used and can be immediately loaded if good primary stability is achieved and with appropriate occlusal loading.	The 3.0mm Intra-Lock® OP Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. They are also indicated for the rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple implants may be restored after a period of delayed loading or placed in immediate function when good primary stability is achieved with appropriate occlusal loading in order to restore normal teeth function. 3.75mm, 4.0mm and 4.75mm Intra-Lock® OP Dental Implants: Intra-Lock®) implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth	Mini Drive-Lock™ Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications. Mini Drive-Lock TM Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.	The Park Dental Research Corporation's LEW O-ball implant system is a self-tapping titanium threaded screw indicated for long-term intra-bony applications. Additionally, the LEW Mini O-ball implant may be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention. The 2.0mm , 2.5 mm, and 3.0 mm diameter are intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches.	The MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full partial endentulism, and employing minimally invasive surgical intervention.

		replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.			

Summary of Substantial Equivalence Comparison

The Mostdi Dental Implant System has the same device characteristics as the predicate devices. Intended use, material, design and use concept are similar.

Slight differences in design characteristics do not affect the application of the device. Therefore, we state that Mostdi™ dental implants is substantially equivalent to predicate devices.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Mostdi Innovations Sdn Bhd concludes that Mostdi Dental implant System is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

Mostdi Innovations Sdn Bhd
C/O Ms. Susan Park
Kodent, Incorporated
325 North Puente Street, Unit B
Brea, CA 92821

Re: K132178
Trade/Device Name: Mostdi Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 1, 2014
Received: April 1, 2014

Dear Ms. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
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Enclosure

Indications for Use

510(K) Number (if known) K132178

Device Name: Mostdi Dental Implant System

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Prescription Use _____X_____ AND/OR Over The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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